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Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 7

Complete if Known

Application Number	10/727,565
Filing Date	December 5, 2003
First Named Inventor	Thomas PICCARIELLO et al.
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	54719.000099

## U.S. PATENT DOCUMENTS

Class / Subclass

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
JR	1.	3331814		Randall	07/18/1967	528/327
JR	2.	3975342		Gross	08/17/1976	530/363
JR	3.	3998799		Bodor et al.	12-21-1976	560/251
JR	4.	4040907		Ullman et al.	08/09/77	435/188
JR	5.	4224316		Momany	09/23/1980	514/117
JR	6.	4297346		Rips et al.	10-27-1981	514/119
JR	7.	4358604		Albarella et al.	11/09/1982	560/40
JR	8.	4399121		Albarella et al.	08/16/83	530/363
JR	9.	4426453		Cree et al.	01/17/1984	436/500
JR	10.	4427660		Schiffman et al.	01/24/1984	514/118
JR	11.	4457907		Porter	07-1984	424/10.3
JR	12.	4483807		Asano et al.	11/20/1984	264/460
JR	13.	4490221		Collange et al.	12/25/1984	205/435
JR	14.	4552864		Antoni et al.	11/12/85	514/115
JR	15.	4650675		Borel et al.	03/17/1987	
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JR	17.	4657873		Gadow et al.	04/14/1987	436/532
JR	18.	4766121		Ellis et al.	08/23/1988	514/247
JR	19.	4801575		Pardridge	01/31/1989	514/4
JR	20.	4902505		Pardridge et al.	02/20/1990	424/85.7
JR	21.	4960790		Stella et al.	10/02/1990	514/449
JR	22.	4976962		Bichon et al.	12/11/90	424/424
JR	23.	5073641		Bundgaard et al.	12/17/1991	560/56
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JR	25.	5219564		Zalipsky et al.	06/15/1993	424/178.17
JR	26.	5225204		Chen et al.	07/06/1993	424/484
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JR	30.	5534496		Lee et al.	07/09/96	514/17
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JR	33.	5756291		Griffin et al.	05/26/1998	435/6
JR	34.	5762909		Uzgiris	06/09/98	424/9.34

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Jeffrey E. Russel

Date  
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January 13, 2005

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Sheet 2 of 7

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JR	35.	5767227		Latham et al.	06/16/98	530/324
JR	36.	5846743		Janmey et al.	12/08/98	435/78
JR	37.	5891459		Cooke et al.	04-1999	424/439
JR	38.	5898033		Swadesh et al.	04/27/1999	514/224.2
JR	39.	5910569		Latham et al.	06/08/99	530/324
JR	40.	5935995		Bosslet et al.	08/10/1999	514/460
JR	41.	6062294		Lazo et al.	09/14/1999	
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JR	46.	6043230		Arimilli et al.	03/28/2000	
JR	47.	6043230		Arimilli et al.	03/28/2000	514/81
JR	48.	6048736		Kosak	04/11/2000	436/536
JR	49.	6074659		Kunz et al.	06/13/2000	424/423
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JR	57.	US2002/0151526		Gallop et al.	10/17/2002	514/143
JR	58.	US2002/0151529		Cundy et al.	10/17/2002	514/169

Examiner Signature

Jeffrey E. Russel

Date Considered

January 13, 2005

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Sheet	3	of	7
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Attorney Docket Number	54719.000099
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## FOREIGN PATENT DOCUMENTS

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#### OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

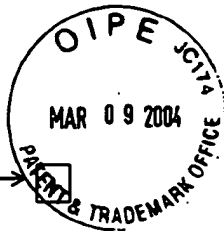
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JR	64.	CANARIS, G., "The Colorado Thyroid Disease Prevalence Study," Archives Internal Medicine Articles and Abstracts, Vol. 160, No. 4 (2000), <i>pages</i> 526-534.	
JR	65.	BUNEVICIUS, R., "Effects of Thyroxine as Compared with Thyroxine Plus Triiodothyronine in Patients with Hypothyroidism," <i>The New England Journal of Medicine</i> , Vol. 340, No. 6 (1999), <i>pages</i> 424-429.	
JR	66.	TOFT, A., "Thyroid Hormone Replacement - One Hormone or Two?," <i>The New England Journal of Medicine</i> , Vol. 340, No. 6 (1999), <i>pages</i> 467-470.	
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JR	69.	AMIDON, G., et al., "A Theoretical Basis for a Biopharmaceutic Drug Classification: The Correlation of <i>in Vitro</i> Drug Product Dissolution and <i>in Vivo</i> Bioavailability," <i>Pharmaceutical Research</i> , Vol. 12, No. 3 (1995), <i>pages</i> 413-	420

Examiner Signature	Jeffrey E. Russel	Date Considered	January 13, 2005
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		Filing Date	December 5, 2003
		First Named Inventor	Thomas PICCARIELLO et al.
		Group Art Unit	Unassigned
		Examiner Name	Unassigned
Sheet 4 of 7	Attorney Docket Number	54719.000099	

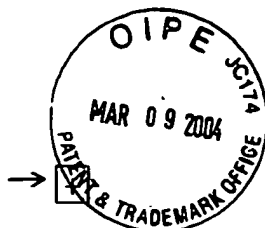
OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
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JR	70.	KOVACS, J., "Glutamic and Aspartic Anhydrides. Rearrangement of N-Carboxyglutamic 1,5-Anhydride to the Leuchs' Anhydride and Conversion of the Latter to Pyroglutamic Acid," 85:1839-1844. (6-20-1963)	
JR	71.	ZUNINO, Franco, et al., "Anti-Tumor Activity of Daunorubicin Linked to Poly L-Aspartic Acid," <i>Int. J. Cancer</i> , 30:465-470 (1982).	
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JR	73.	NISHIDA, Koyo, et al., "Pharmacokinetic Analysis of <i>in Vivo</i> Metabolism of Amino Acid or Dipeptide Conjugates of Salicylic Acid in Rabbit Intestinal Microorganisms," <i>Pharmaceutical Research</i> , 11(1):160-164 (1994).	
JR	74.	SCHMIDT, Brigitte F., et al., "Peptide-Linked 1,3-Dialkyl-3-acyltriazines: Gastrin Receptor Directed Antineoplastic Alkylating Agents," <i>Journal of Medicinal Chemistry</i> , 37(22):3812-3817 (1994).	
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JR	78.	HOFFENBERG, R., et al., "The Application of Mass Spectrometry to the Study of Thyroxine and Related Compounds in Biological Fluids," <i>Mass Spectrometry in Biochemistry and Medicine</i> , pp. 303-312 (1974).	
JR	79.	PERISICO, F.J., et al., "Effect of Tolmetin Glycine Amide (McN-4366), a Prodrug of Tolmetin Sodium, on Adjuvant Arthritis in the Rat," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , 247(3):889-896 (1986).	
JR	80.	SMITH, Richard H., et al., "1,3-Dimethyl-3-acyltriazines: Synthesis and Chemistry of a Novel Class of Biological Methylating Agents," <i>J. Org. Chem.</i> 51(20):3751-3757 (1986).	

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JR	81.	SMITH, R. H., et al., 1,3-Dialkyl-3-acyltriazines, A Novel Class of Antineoplastic Alkylating Agents," <i>Journal of Medicinal Chemistry</i> , 33(9):2579-2583 (1990).	
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JN	93.	DE VRUEH, Remco L.A., et al., "Transport of L-Valine-Acydovir Via the Oligopeptide Transporter in the Human Intestinal Cell Line, Caco-2," <i>Journal of Pharmacology and Experimental Therapeutics</i> , 286(2):1166-1170 (1998).	
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JN	96.	AGGARWAL, et al., "Synthesis and Biological Evaluation of Prodrugs of Zidovudine," <i>J. Med. Chem.</i> , 33(5):1505-1511 (1990).	
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JN	98.	HAVRANOVA, Marie et al., "A High-Molecular Mass Derivative of Trypsin-Kallikrein Inhibitor for Potential Medical Use, II," <i>Hoppe-Seyler's Z. Physiol. Chem.</i> , 363:295-303 (1982).	
JN	99.	RYSER, Hugues J.P., et al., "Conjugation of Methotrexate to Poly (L-lysine) Increases Drug Transport and Overcomes Drug Resistance in Cultured Cells," <i>Proc. Natl. Acad. Sci. USA</i> , 75(8):3867-3870 (1978).	
JN	100.	HAN, Hyo-Kyung, et al., "Targeted Prodrug Design to Optimize Drug Delivery," <i>AAPS PharmSci</i> , 2(1): Article 6 (2000).	
JN	101.	TAMAI, I., et al., "Improvement of L-dopa Absorption by Dipeptidyl Derivation, Utilizing Peptide Transporter PepT1," <i>J. Pharma. Sci.</i> , 87(12):1542-1546 (1988), Abstract.	
JN	102.	OH, DM, et al., "Drug Transport and Targeting. Intestinal Transport," <i>Pharma Biotechnol.</i> , 12:59-88 (1999), Abstract.	
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JN	104.	KNUTTER, I, et al., "A Novel Inhibitor of the Mammalian Peptide Transporter PEPT1," <i>Biochemistry</i> , 40(14):4454-4458 (2001), Abstract.	

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/727,565
		Filing Date	December 5, 2003
		First Named Inventor	Thomas PICCARIELLO et al.
		Group Art Unit	Unassigned
		Examiner Name	Unassigned
Sheet 7 of 7	Attorney Docket Number	54719.000099	

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
JR	105.	SHEN, H., et al., "Developmental Expression of PEPT1 and PEPT2 in Rat Small Intestine, Colon, and Kidney," <i>Pediatr Res</i> , 49(6):789-795 (2001), Abstract	
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JR	107.	HAN H., et al., "5'-Amino Acid Esters of Antiviral Nucleosides, Acyclovir, and AZT and Absorbed by the Intestinal PEPT1 Peptide Transporter," <i>Pharm Res</i> , 15(8):1154-1159 (1998), Abstract.	
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Examiner Signature	Jeffrey E. Russel	Date Considered	January 13, 2005
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